UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,575	06/26/2003	David Edgren	ARC3234R1	4693

27777 7590 09/13/2006

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,575	EDGREN, ET. AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date : 4/4/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants': (1) Response to Restriction Requirement filed on 14 August 2006; (2) Petition for Extension of Time filed on 14 August 2006; and (3) IDS filed on 1 April 2005.

Election/Restrictions

Applicant's election without traverse of Group II (claims 25-29) with newly added claims 30-46 in the reply filed on 14 August 2006 is acknowledged.

Claims 1-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 14 August 2006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-31, 41, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Bhatt, *et. al.* (U.S. Patent No. 6,368,626).

Bhatt, *et. al.* disclose a controlled release oral dosage form (*see* col. 3, lines 10-31). The disclosed dosage form is the instant dosage form, as claimed:

- the once-a-day administration of claim 25 (see col. 7, line 8);

- the core comprising: (a) a low solubility therapeutic agent (e.g. dixoxin – see col. 7, line 63); (b) a structural polymer (*see* col. 19, line 25); and (c) the soluble surfactant of instant claim 25 (*see* col. 13, line 6);
- the semi-permeable membrane surrounding the core of instant claim 25 (*see* col. 3, line13);
- the exit orifice of instant claim 25 (*see* col. 3, line 12);
- the extended release of instant claim 25 (*see* col. 7, line 6);
- the zero order release rate of instant claim 26 (see figure 3);
- the ascending release rate of instant claim 27 (see figure 7);
- the high dose of low solubility therapeutic agents of instant claim 28 (*see* col. 6, line 55);
- the method for enhancing the bioavailability of a therapeutic agent by administration said dosage form to a subject of instant claim 29 (*see* col. 3, line 40);
- the release of a high dose of therapeutic agent of instant claim 30 (see col. 6, line 55);
- the 20%-90% content of therapeutic agent of instant claim 31 (see col. 6, line 57);
- the 200,000 MW polyethylene oxide of instant claim 41; and
- the poloxamers of instant claim 42 (*see*, col. 20, line 53).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 45 and 46 rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatt, *et. al.* (U.S. Patent No. 6,368,626) in view of *Chen, et. al.* (U.S. 2003/0077297).

Bhatt, *et. al.* disclose a controlled release oral dosage form (*see* above).

Bhatt, *et. al.* explain that their dosage form comprising a core (consisting of a low solubility therapeutic agent, a structural polymer, and a solubilizing surfactant) surrounded by a semi-permeable membrane, and an exit orifice is beneficial in bringing about "...the substantially complete release of a drug from the dosage form, particularly from dosage forms that may require high drug loading in order to have the desired pharmacological effect." *See* col. 6, lines 46-49.

The Bhatt, *et. al.* reference differs from the instant application in that it does not teach the use of the active agent "topiramate" or the solubilizing surfactant "poloxamer 407".

Chen, *et. al.* teach a controlled release oral dosage form (*see* paragraph 0040). The disclosed dosage form may comprise topiramate (*see* paragraph 0068) and poloxamer 407 (*see* table 15).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add topiramate and poloxamer 407 to a controlled release

formulation, as taught by Bhatt, *et. al.* in view of Chen, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to make a dosage form comprising a core (consisting of a low solubility therapeutic agent, a structural polymer, and a solubilizing surfactant) surrounded by a semi-permeable membrane, and an exit orifice because of the beneficial effects substantially complete release of a drug from the dosage form, particularly from dosage forms that may require high drug loading in order to have the desired pharmacological effect, as explained by Bhatt, *et. al.*

2. Claims 32-40, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatt, *et. al.* (U.S. Patent No. 6,368,626)

Bhatt, *et. al.* disclose a controlled release oral dosage form (*see* above).

While Bhatt, *et. al.* do not explicitly teach all the instant claimed percentages and dosage levels, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages and dosages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in percentage and dosage level will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such percentage and dosage level is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ

233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage and dosage level ranges.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of copending Application No. 10/404,166 ('166). Although the conflicting claims are not identical, they are not patentably distinct from each other because '166 claims a controlled release oral dosage form comprising a core, a semi-permeable membrane, and an exit orifice. *See* claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

***

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600